27. (NEW) An isolated and/or purified polynucleotide comprising one or more of:

(a) a polynucleotide encoding a polypeptide comprising SEQ ID NO 2 or SEQ ID NO: 6;

(b) a polynucleotide comprising a nucleotide sequence of SEQ ID NO: 1 or SEQ ID NO: 5;

(c) a polynucleotide, wherein the complement of said polynucleotide hybridizes to the full length coding sequence of (a) or (b) under high stringency;

(d) a polynucleotide comprising the cDNA of deposit NCIMB 41074; and

(e) a complement to the polynucleotide of any one of (a), (b), (c), or (d).

28. (NEW) A polynucleotide of any one of claims 24 to 27, further comprising the use of said polynucleotide or the polypeptide encoded for by said polynucleotide in an analytical or functional assay.

29. (NEW) A polynucleotide of any one of claims 24 to 27, further comprising a nucleotide sequence having at least 95% sequence identity to said polynucleotide.

30. (NEW) A polynucleotide of any one of claims 24 to 27, wherein said polynucleotide further comprises a nucleotide sequence consisting of a fragment of said polynucleotide.

31. (NEW) A polynucleotide of any one of claims 24 to 27 or 30, wherein said polynucleotide encodes for a cysteinyl leuotriene receptor.

32. (NEW) A polynucleotide of any one of claims 24 to 27 or 30, wherein said polynucleotide encodes for a CysLT2 receptor.

33. (NEW) A vector comprising the polynucleotide of any one of claims 24 to 27 or 29 to 30.

REMARKS:

1. Claims 1-22 are pending in the application.

2. Claims 7-21 are being canceled without waiver or prejudice, subject to the right to file a divisional application(s) thereto.

3. The Examiner accurately notes Applicant's earlier election with traverse of Group I in Paper No. 6. Applicant's traversal requested the joining of Groups I and II. The Examiner has found the traversal persuasive and the claims of Groups I and II, Claims 1-6 and 22 were under examination in the Office Action mailed March 25, 2002.

4. Claims 23-33 are being added to even more clearly show that which Applicant considers his invention. Support for this amendment is found, for example, at page 4 lines 24-29, page 4 lines 31-33, page 13 lines 13-17, page 14 lines 28-31, page23 lines5-8, page 52 lines 11-31 and in the claims as originally filed, hence the Examiner will appreciate that no new matter is being added by the proposed new claims.

5. After entry of the amendments hereinabove Claims 1-6 and 22-33 remain pending in the application.

6. The Examiner has requested correction of Fig. 2 for compliance with MPEP 2422.02. Applicant provides hereto as an attachment a hand-marked amendment to Fig. 2 in red ink for approval by the Examiner. Upon approval of the Examiner a substitute drawing will be provided. Applicant further requests the Examiner to inquire about the status of the review by the USPTO Draftsperson of the drawings of the present application.

In regard to Figs. 6 and 7, Applicant acknowledges that the Sequence Listing section of the specification notes the sequences contained in Figs. 6 and 7 but in a different format. Applicant therefore would prefer to retain Figs. 6 and 7 as part of the specification.

7. The Examiner has noted the use of trademarks in the specification. Applicant acknowledges the proprietary nature of trademarks and will make every effort to prevent a use of a trademark within the specification that might adversely affect its validity.

8. The specification has been amended to remove the URL noted at page 23 and to

provide in its place a non-executable name of the same database.

9. Claim 4 was objected to under 37 C.F.R. §1.75(c) as being in improper form because a multiple dependent claim 4 depends from claim 1 and claim 4. Accordingly, claim 4 was not further treated on the merits. Applicant respectfully traverses this objection.

Claim 4 has now been amended to be dependent solely on claim 3. It is submitted

that this amendment moots the objection of claim 4 under 37 C.F.R. §1.75(c). Applicant respectfully requests that claim 4, as amended, now be examined on its merits.

10. Claim 5 was objected to under 37 C.F.R. § 1.75(c) as being of improper dependent form for failing to further limit the subject matter of the previous claim. Claim 6 was also not considered on its merits on the basis of the objection to claim 5. Applicant respectfully traverses the objection to claims 5 and 6.

Claim 5 has been amended to correct the dependency rejection, by amending claim 5

to be dependent from claim 4 as correctly noted by the Examiner. In addition, the amendment to claim 5 further moots the objection of the claim as being of improper dependent form for failing to further limit the subject matter of the previous claim. The amended claim now calls for the production of a polypeptide fragment, which is more narrow than the expression of a polypeptide in claim 4. Support for this amendment is found in the specification at page 34, lines 24-26, page 12, lines 18-23 and page 29, lines 12-18. As a result of the amendment to claim 5 the objection to claim 6 should also be mooted.

Applicant respectfully requests that Claims 5 and 6 now be examined on their merits.

11. Claims 1-3 and 22 were rejected under 35 U.S.C. §101 on the basis that the claimed invention is drawn to an invention with no apparent or disclosed specific and substantial credible utility. The Examiner has noted that the application provides a description of an isolated DNA encoding a protein and the protein encoded thereby. The Examiner argues moreover that the application does not disclose the biological role of this protein or its significance. The Examiner has also argued that the specification does

not disclose a credible "real world" use of the encoded protein and therefore the claimed invention is incomplete and, therefore does not meet the requirements of 35 U.S.C. §101 as being useful. Applicant respectfully traverses this rejection.

It is respectfully submitted that the Office Action has not established a prima facie case that the claimed invention is drawn to an invention with no apparent or disclosed specific and substantial credible utility.

To meet the utility requirement the Supreme Court in *Mitchell v. Tilghman*, 86 US 287 (1873), has held a new product or process must be shown to be "operable" – that is, it must be "capable of being used to affect the object proposed". Cases subsequent to the *Mitchell* decision have not, interpreted this language in *Mitchell* to mean that a patented product must accomplish all objectives stated in the specification. When a properly claimed invention meets at least one stated objective, utility under §101 is clearly shown." *Raytheon Co. v. Roper Corp., 220* USPQ 592,598 (Fed. Cir. 1983), cert. denied, 469 U.S. 835 [225 USPQ 232] (1984). See also *Carl Zeiss Stiftung v. Renishaw,* 20 USPQ2d 1094,1100 (Fed. Cir. 1991). It is respectfully submitted that the teachings of Applicant's specification and the claims are in full compliance with the utility requirements of §101.

Applicant draws the Examiner's attention to the example at page 73, line 13 to page 74 line 16, which provides data supporting a biological function of PFI-017 as a leukotrine receptor. The example clearly provides support for the utility of the present invention. *In re Langer* makes clear that a §101 rejection may be overcome by suitable proofs that the statement of utility and its scope as defined in the specification are true. 183 USPQ 288, 297 (CCPA 1974).

It is also noted that in vitro tests also provide a way to overcome a §101 rejection. See *Ex parte Bhide*, 42 USPQ 2D 1441,1448 (USPTO BPA 1996). Such analytical tests are described at page 56 line 26 to page 61, line 5. Each of the described tests may be performed by one of skill in the art. The proofs of utility need only be convincing to one skilled in the art and this is dependent on the facts of each individual case. *In re Buting,* 169 USPQ 689,690 (CCPA 1969).

The Office Action relies on the decision of *Brenner v. Mason* to support the instant §101 rejection of the claims for lacking utility. Applicant respectfully disagrees

with this position as the *Brenner* decision was directed to a set of distinct facts and issues developed in the patent application under appeal. The Supreme Court in *Brenner* in construing the term "useful" in §101 of the Patent Act noted that:

"As is so often the case, however, a simple, everyday word can be pregnant with ambiguity when applied to the facts of life. That this is so demonstrated by the present conflict between the Patent Office and the CCPA over how the test is to be applied to a chemical process which yields an already known product whose utility – other than as a possible object of scientific inquiry – has not yet been evidenced."[1]

In view of the foregoing, Applicant respectfully requests reconsideration of the Office Action mailed March 25, 2002.

12. Claims 1-3 and 22 were rejected under 35 USC §112 first paragraph on the basis that the claimed invention was not supported by either a clear asserted utility or a well-established utility for reasons set forth in the rejection of the claims under 35 U.S.C. §101 for lack of utility. Applicant respectfully traverses this rejection.

It is respectfully submitted that the Office Action has not established a prima facie case that the claimed invention is not supported by either a clear or asserted utility or a well-established utility that one skilled in the art would not know how to use the claimed invention. Applicant respectfully notes that as the requirements for utility under §101 have now been properly met for the reasons stated above, the instant rejection under 35 U.S.C. §112, first paragraph should thus be mooted.

In addition, claims 1-3 and 22 meet the enablement requirement of § 112, first paragraph based on the disclosure of representative nucleotide and amino acid sequences in the specification, the teachings of the specification, e.g. the example noted above and the deposit of NCIMB 41074. The teachings of Applicant provide to the public how the claimed invention can be utilized.

In view of the foregoing Applicant respectfully requests reconsideration of the Office Action mailed March 25, 2002.

13. Claim 2 was rejected under 35 U.S.C. §112 first paragraph as containing

[1] *Brenner v. Mason,* 148 USPQ 689,693 (US 1966).

subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains or with which it is most clearly connected to make the invention. Applicant respectfully traverses this rejection.

Claim 2 has been amended to limit the polynucleotide of claim 1 to one of parts (a),
(b), or (c). It is respectfully submitted that this amendment moots the instant rejection of Claim 2 under 35 U.S.C. §112, first paragraph.

Applicant acknowledges the Examiner's notation in the record that the specification provides guidance needed for producing nucleic acid molecule of SEQ. ID NO: 1 that encodes the amino acid sequence of SEQ. ID NO: 2. Applicant further notes that in view of Applicant's teaching of SEQ. ID NO: 1 and SEQ. ID NO: 2 one of skill in the art would be enabled to modify these sequences in accordance with the teaching of Applicant's specification or by knowledge in the art.

In view of the foregoing, Applicant respectfully requests reconsideration of the Office Action mailed March 25, 2002.

14. Claims 1-3 and 22 were rejected under 35 U.S.C. §112, first paragraph as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the art that the inventor at the time the application was filed had possession of the claimed invention. Applicant respectfully traverses this rejection.

The Examiner has noted that the enablement requirement for this rejection may be satisfied by a deposit of the plasmid and/or microorganism. The Examiner has correctly noted that Applicant had deposited the organism, but there was no indication in the specification as to public availability. Applicant's attorney notes for the record that the deposit as noted in the specification at page 69, line 21 to page 70, line 7 has been made under the Budapest Treaty and that the strain will be irrevocably and without restriction or condition released to the public upon the issuance of a patent.

In view of the foregoing attorney's statement in the record, Applicant respectfully requests reconsideration of the Office Action mailed March 25, 2002.

15. Claims 1-3 were rejected under 35 U.S.C. §112 second paragraph as being indefinite for failing to point out and distinctly claim the subject matter which applicant regards as the invention. Applicant respectfully traverses this rejection.

The Examiner has rejected Claim 1 as being indefinite for recitation of "stringent" hybridization conditions. Applicant has amended Claim 1 to make moot this rejection. In addition, the conditions of "moderate stringency" are defined in the specification at page 24, lines 19-22. Claims 2 and 3 were rejected as being indefinite for being dependent upon claim 1. In view of the amendment of claim 1 to moot the §112 second paragraph rejection it is respectfully submitted that the rejection of claims 2 and 3 are also now muted.

In view of the foregoing, Applicant respectfully requests reconsideration of the Office Action mailed March 25, 2002.

16. Attached hereto is a marked-up version of the changes made to the claims by the current amendment. The attached page is captioned **Marked Version to Show Amendments**.

Applicant believes that the amendments hereinabove to the claims and the remarks place the application in a condition for allowance. Therefore, entry of the amendments hereinabove and reconsideration of the Office Action mailed March 25, 2002 are respectfully requested. Such prompt and favorable action is earnestly solicited.

The Examiner is respectfully urged to contact the undersigned attorney for purposes of favorably advancing the prosecution of the application.

Respectfully submitted,

Date: September 20, 2002

Nicholas I. Slepchuk, Jr.
Attorney for Applicant(s)
Reg. No. 32,174

Pfizer Inc.
Patent Department, MS 8260-1611
Eastern Point Road
Groton, Connecticut 06340
(860) 715-0081

CERTIFICATE OF FIRST CLASS MAIL

I hereby certify that this correspondence is being transmitted to the United States Patent Office as first-class mail in an envelope addressed to Hon. Commissioner for Patents on this 20th day of September 2002.

By: Heather Randhahn
Heather Randhahn

MARKED VERSION TO SHOW AMENDMENTS

IN THE SPECIFICATION:

At page 23 lines 5-14, please rewrite the paragraph as follows:

As indicated, for some applications, sequence homology (or identity) may be determined using any suitable homology algorithm, using for example default parameters. For a discussion of basic issues in similarity searching of sequence databases, see Altschul *et al.* (1994) Nature Genetics 6:119-129. For some applications, the BLAST algorithm is employed, with parameters set to default values. The BLAST algorithm is described in detail at [http://www.ncbi.nih.gov/BLAST/blast_help.html] the NCBI database. Advantageously, "substantial homology", when assessed by BLAST, equates to sequences which match with an EXPECT value of at least about e-7, preferably at least about e-9 and most preferably e-10 or lower. The default threshold for EXPECT in BLAST searching is usually 10.

IN THE CLAIMS

Please amend Claims 1-2 and 4-6 as follows:

1. (AMENDED) An isolated and/or purified polynucleotide comprising one or more of:
   (a) a polynucleotide encoding a polypeptide comprising SEQ ID NO: 2 or SEQ ID NO: 6;
   (b) a polynucleotide comprising a nucleotide sequence of SEQ ID NO: 1 or SEQ ID NO: 5;
   (c) a polynucleotide, wherein the complement of said polynucleotide hybridizes to the full length coding sequence of (a) or (b) under [conditions of] moderate stringency;
   (d) a polynucleotide comprising the cDNA of deposit NCIMB 41074; and
   (e) a complement to the polynucleotide of any one of (a), (b), (c), or (d).

2. (AMENDED) The polynucleotide of claim 1, parts (a), (b), or (c), wherein said polynucleotide encodes a G-protein coupled receptor (GPCR).

4. (AMENDED) A host cell transformed or transfected with the vector of claim 3, wherein said host cell expresses [the polynucleotide of claim 1] a polypeptide of SEQ ID NO: 2 or SEQ ID NO: 6 under conditions sufficient for expression of the [polynucleotide] polypeptide.

5. (AMENDED) A process for producing a polypeptide [or] fragment thereof comprising culturing the transformed/transfected host cell of claim [5] 4 under conditions sufficient for the expression of said polypeptide [or] fragment.

6. (AMENDED) A membrane preparation of a cell of claim 4 or 5.

Figure 2

ClustalW Alignment of PFI-017 with Cysteinyl Leukotriene Receptor

```
                    1                                                   70
PFI-017      (1) MEPNGTFSNN-NSRNCTIENFKREFEPIVYLIIFFWGVLGNGLSIYVFLQPYKKSTSVNVFMINLAISDL
CysLT1       (1) MDETGNLIVSSATCHDTIDDFRNQVYSTLYSMISVVGFFGNGFVLYVLIKTYHKKSAFQVYMINLAVADL
Consensus    (1) MD  G  S    S   TID FK   F  LY II   G  GNG  IYV I  Y K SA NVFMINLAIADL
                    71                                                  140
PFI-017     (70) LFISTLPFRADYYLRGSNWIFGDLACRIMSYSLYVNMYSSIYFLTVLSVVRFLAMVHPFRLMHVTSIRSA
CysLT1      (71) LCVCTLPLRVVYYVHKGIWIFGDFLCRLSTYALYVNLYCSIFFMTAMSFFRCLAIVFPVQNTNIVLQKKA
Consensus   (71) L I TLP R  YYL    WIFGD  CRI SYALYVNLY SIFFLT LS  R IAIV P   I L S K A
                    141                                                 210
PFI-017    (140) WIFGCGIIWILIMASSIMLLDSGSEQN-GSVTSCLELNLYKIAK--LQTMNYIALVVGCLLPFFTLSICYL
CysLT1     (141) RFVCVGIWIFVLLTSSPFLMAKPQKDEKNNTKCFEPPQDNQTKNHVLVLHYVSLFVGFLIPFVIIIVCYT
Consensus  (141)   LC  IWI II SS   L A         T C E       K  L  L YIAL VG IIPF  I ICY
                    211                                                 280
PFI-017    (207) LIIRVLLKVEVPESGLRVSHRKAITTIIIITLIIFFLCFLPYHTLRTVHLTTWK--VGLCK--DRLHKALV
CysLT1     (211) MIILTLLKKSMKKN--LSSHKKAIGMIMVVTAAFLVSFMPYHIQRTIHLHFLHNETKPCDSVLRMQKSVV
Consensus  (211) LII  LLK  M       SHKKAI  III    F L FLPYH  RTIHL         C    RL KALV
                    281                                                 340
PFI-017    (273) ITLALAAANACFNPLLYYFAGENFKDRLKSALRKGHPQKAKTKCVFPVSVWLRKETRV--
CysLT1     (279) ITLSLAASNCCFDPLLYYFSGGNFRKRLS-TFRKHSLSSVTYVPRKKASIPEKGEEICKV
Consensus  (281) ITLALAAAN CF PLLYFFAG NFK RL    RK              SL  K E
```

(SEQ ID NO: 2)